K003759

JUN 2 8 2001

Summary of Safety and Effectiveness Information	AESCULAP® INC.
Premarket Notification, Section 510(k)	FEBRUARY 9, 2001

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Trade Name: Aesculap® - Spiegelberg Brain Pressure Monitoring System
Common Name(s): Intracranial pressure monitor
Classification Name(s): Intracranial pressure monitoring device

Establishment Name & Registration Number:
Name: Aesculap® Inc.
Number: 2916714

Classification(s):
§ 882.1620 Intracranial pressure monitoring device.
(a) Identification. An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.
(b) Classification. Class II (performance standards).

Device Class: Class II for all requested indications
Classification Panel: Neurosurgical Devices Panel
Product Code(s): 84GWM

Applicant Name & Address:
Aesculap® Inc.
944 Marcon Blvd.
Allentown, PA 18109
650.624.5070

Company Contact:
Ms. Joyce Thomas
Aesculap® Inc.
944 Marcon Blvd.
Allentown, PA 18109
650.876.7000 voice - 650.876.0266 fax

Submission Correspondent:
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C -100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

Special Controls:
The Aesculap® - Spiegelberg Brain Pressure Monitoring System complies with the following special controls:
(i) Compliance with material standards,
(ii) Compliance with biocompatability standard, and
(iii) Labeling

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Labeling:
The Aesculap® - Spiegelberg Brain Pressure Monitoring System discussed in this premarket notification will be manufactured by Spiegelberg and labeled with the Aesculap logo. The system will be marketed exclusively to healthcare facilities and physicians.

Preamendments Device (legally marketed comparison device):
AESCULAP® Inc. believes that the Codman Intracranial Pressure Monitor (991222) and the Integra NeuroCare, Camino (K962928) devices are substantially equivalent.. A basic feature comparison table for the Aesculap® - Spiegelberg Brain Pressure Monitoring System is located at the end of this document.

Summary Basis for Equivalence and Comparison Table:
Based on performance testing and the available product information concerning the referenced comparison device, the Aesculap® - Spiegelberg Brain Pressure Monitoring System is similar in that:

- The devices have the same intended use and indications for use.
- The devices are made of the same or substantially similar materials.
- The devices have similar form, function, procedure and features.
- Performance characteristics are suitable for the designated indications for use

The use of ISO/QSR based process controls, testing, materials standards (ASTM and ISO) and the marked similarities of the referenced comparison device establishes that the Aesculap® - Spiegelberg Brain Pressure Monitoring System is substantially equivalent. Based on this, the anticipated clinical performance of the Aesculap® - Spiegelberg Brain Pressure Monitoring System is equivalent to the referenced system.

Summary Comparison Table:

FEATURE	Aesculap® - Spiegelberg Brain Pressure Monitoring System	Integra NeuroCare	Codman	SE?
Indications for Use:	The Aesculap® - Spiegelberg Brain Pressure Monitoring System is indicated for use in those conditions where continuous monitoring of intracranial pressure is required. As dictated by clinical judgment, direct measurement of intracranial pressure (ICP) may be obtained from subdural, parenchymal or intraventricular probe locations.	SAME	SAME	YES
Brain Probes:	3 locations, 6 styles	3 locations, 3 styles	3 locations, 4 styles	YES
Sterility:	Ethylene Oxide	SAME	SAME	YES
Non-fluid coupling:	Yes	Yes	Yes	YES
Materials:	Polyurethane	Unknown	Nylon & titanium	YES
Auto Zero:	Yes	No	No	YES
Manufacturer:	Spiegelberg	Camino Neurocare	Codman	YES
Monitoring Sites:	Dura Parenchymal Ventricular	SAME	Dura Parenchymal Ventricular	YES
Transducer Location:	ICP Monitor	Catheter Tip	Catheter Tip	NO
CPP Monitor:	Yes	Yes	No	YES
Product Code:	84GWM	SAME	84GWM	YES
K - Number:	Pending	K962928	K991222	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2001

Aesculap, Inc.
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane
Suite C-100
Pleasant Hill, California 94523

Re: K003759
Trade/Device Name: Aesculap® - Spiegelberg Brain Pressure Monitoring System
Regulation Number: 882.1620
Regulatory Class: II
Product Code: GWM
Dated: June 11, 2001
Received: June 13, 2001

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K003759

Device Name(s): Aesculap® - Spiegelberg Brain Pressure Monitoring System

Indications for Use:

The Aesculap® - Spiegelberg Brain Pressure Monitoring System is indicated for use in those conditions where continuous monitoring of intracranial pressure is required. As dictated by clinical judgment, direct measurement of intracranial pressure (ICP) may be obtained from subdural, parenchymal or intraventricular probe locations.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003759

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)